

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BIODELIVERY SCIENCES INTERNATIONAL,)
INC. and ARIUS TWO, INC.,)

Plaintiffs,)

v.)

C.A. No. 18-1395 (CFC) (CJB)

ALVOGEN PB RESEARCH & DEVELOPMENT)
LLC, ALVOGEN MALTA OPERATIONS LTD.,)
ALVOGEN PINE BROOK LLC, ALVOGEN,)
INC., and ALVOGEN GROUP, INC.,)

Defendants.)

BIODELIVERY SCIENCES INTERNATIONAL,)
INC. and ARIUS TWO, INC.,)

Plaintiffs,)

v.)

C.A. No. 19-444 (CFC) (CJB)

CHEMO RESEARCH, S.L., INSUD PHARMA)
S.L., INTELGENX CORP., and INTELGENX)
TECHNOLOGIES CORP.,)

Defendants.)

~~PROPOSED~~ CLAIM CONSTRUCTION ORDER

WHEREAS, Plaintiffs BioDelivery Sciences International, Inc. and Arius Two, Inc. and Defendants Alvogen PB Research & Development LLC, Alvogen Malta Operations Ltd., Alvogen Pine Brook LLC, Alvogen, Inc., Alvogen Group, Inc., Chemo Research, S.L., Insud Pharma S.L., IntelGenx Corp., and IntelGenx Technologies Corp. submitted briefing and made appearances on December 20, 2019, in support of their respective claim construction positions.

Having considered the submissions of the parties, the arguments of counsel, and for the reasons articulated by the Court at the December 20, 2019 *Markman* hearing, the Court adopts

the following constructions for the following terms of U.S. Patent Nos. 8,147,866 (“the ’866 patent”); 9,655,843 (“the ’843 patent”); and 9,901,539 (“the ’539 patent”):

I. CLAIM TERMS CONSTRUED AT *MARKMAN*

A. The ’866 Patent

Claim Term	Construction
“a bioerodable mucoadhesive layer” (Claims 1-12)	“a bioerodable mucoadhesive layer”
“a barrier layer” (Claims 1-12)	“a barrier layer”
“is a buffered environment” (Claims 1-12)	“is a buffered environment”
“a pH of between about 4 and about 6” (Claims 1, 4-8, 11-12) ¹	“a pH of between approximately 4 and approximately 6”

B. The ’843 Patent

Claim Term	Construction
“a bioerodable mucoadhesive layer” (Claims 1-25)	“a bioerodable mucoadhesive layer”
“a polymeric barrier environment” (Claims 1-25)	“a polymeric barrier environment”
“a pH of between about 4 and about 7.5” (Claims 1-3, 5-6, 13-15, 17-18) ²	“a pH of between approximately 4 and approximately 7.5”

¹ The construction of “about” also applies to dependent claims 2-3 and 9-10, which recite the “about” term but with a narrower pH range.

² The construction of “about” also applies to dependent claims 4 and 16, which recite the “about” term but with a narrower pH range.

“has a pH buffered to between about 4 and about [6/7.5]” (Claims 7-12, 19-25)	“has a pH buffered to between approximately 4 and approximately [6/7.5]”
“transmucosal” (Claims 1-12)	“any route of administration via a mucosal membrane, including, but not limited to, buccal, sublingual, nasal, vaginal, and rectal”
“third layer or coating” (Claims 6, 12, 18, 24)	“third layer or coating”

C. The '539 Patent

Claim Term	Construction
“a bioerodable mucoadhesive layer” (Claims 1-22)	“a bioerodable mucoadhesive layer”
“a barrier layer” (Claim 8)	“a barrier layer”
“a backing layer” (Claims 1-22)	“a backing layer”
“buffered to a pH” (Claims 1-22)	“buffered to a pH”
“a pH of between about 4.0 and about 6.0” (Claims 1-8 and 10-22) ³	“a pH of between approximately 4.0 and approximately 6.0”
“a pH of between about 4.0 and about 4.8” (Claims 1-22)	“a pH of between approximately 4.0 and approximately 4.8”

³ The construction of “about” also applies to claim 9, which recites “a buffered environment having a pH of between about 4 and about 6.”

“an opioid-experienced subject” (Claims 1-22)	“one or more subjects currently receiving opioid therapy”
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II. CLAIM TERMS AGREED UPON BEFORE *MARKMAN*


A. The '866 Patent

Claim Term	Construction
“direct transmucosal” (Claims 1-12)	“mucosal administration via the oral mucosa, e.g., buccal and/or sublingual”

B. The '539 Patent

Claim Term	Construction
“steady-state C_{\max} of plasma buprenorphine concentration” (Claims 1-8, 10-22)	“the state wherein the post dose maximum plasma concentration of buprenorphine does not differ from one dose to another”
“oral mucosal” (Claim 9)	“buccal and/or sublingual”
“steady-state T_{\max} of buprenorphine” (Claim 14)	“time to reach the steady-state C_{\max} of plasma buprenorphine concentration”
“ C_{\min} of buprenorphine” (Claim 15)	“the state wherein the post dose minimum plasma concentration of buprenorphine does not differ from one dose to another”
“steady-state AUC_{last} of buprenorphine” (Claim 16)	“steady-state”: no construction necessary “ AUC_{last} ”: “area under the concentration-time curve from time-zero to the time of the last quantifiable concentration”

SO ORDERED this 23rd day of January, 2020.



The Honorable Colm F. Connolly
United States District Court Judge